



USSN: 10/591,004  
Dkt. No.: 0801-0052.30

*EPW*

**PATENT**

**CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service as priority mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10-26-06  
Date

*[Signature]*  
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:

BODENTEICH, et al.

Serial No.: 10/591,004

Filing Date: August 28, 2006

Title: CONTROLLED RELEASE  
PHARMACEUTICAL COMPOSITIONS  
OF TOLPERISONE FOR ORAL  
ADMINISTRATION

Examiner: Not Yet Assigned

Group Art Unit: Unknown

Confirmation No.: Unknown

Customer No.: 31048

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sirs:

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,  
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.  
§§1.97 and 1.98.

- [X] Pursuant to 37 C.F.R. §1.98, copies of publications B1-B6 and C1-C2 cited in the attached Form PTO/SB/08 are enclosed.
- [X] No copy of the U.S. publications listed on the attached Form PTO/SB/08A are being provided because the Office waives the requirement under 37 C.F.R. 1.98 (a) (2) (i) for submitting a copy of each cited U.S. patent and each U. S. patent application publication for all U.S. national patent applications filed after June 30, 2003

- ☐ No copies of the publications listed on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. \_\_\_\_\_ to which the above-identified application claims priority under 35 U.S.C. §120.
- ☐ Publications \_\_\_\_\_ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to PCT application serial no. \_\_\_\_\_ and mailed on \_\_\_\_\_.
- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_\_\_. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_\_\_. English language publication \_\_\_\_ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication \_\_\_\_\_ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) \_\_\_\_\_ cited in the attached Form PTO/SB/08A.
- ☐ Enclosed is a copy of pending patent Application Serial No. \_\_\_\_\_.


This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

Respectfully submitted,

Date: 10/26/06

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PTO/SB/08A (08-00)

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/591,0004
				Filing Date	August 28, 2006
				First Named Inventor	BODENTEICH et al.
				Group Art Unit	1617
				Examiner Name	Not Assigned
Sheet	1	of	2	Attorney Docket Number	0801-0052.30

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	6,500,455	B1	Frantsits, Werner	12-31-2002
	A2	4,912,116		Itoh, <i>et al.</i>	03-27-1990
	A3	4,702,918		Ushimaru, <i>et al.</i>	10-27-1987
	A4	2002/119197		Dyar Stephen Craig, <i>et al.</i>	08-29-2002

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	B1	WO	00/59508	A1	Sanochemia Pharmazeutika AG	10-12-2000	
	B2	WO	02/060415	A1	Roehm GMBH	08-08-2002	
	B3	JP	53040779		Nippon Kayaku KK	04-13-1978	
	B4	EP	1101490	A1	Tanabe Seiyaku Co.	05-23-2001	
	B5	EP	1238662	A2	Sumitomo Pharma	09-11-2002	
	B6	EP	1252887	A12	Tanabe Seiyaku Co.	10-30-2002	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.  
<sup>2</sup> See attached Kinds of U.S. Patent Documents.  
<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).  
<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.  
<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.  
<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08A (08-00)

<div>Substitute for form 1449A/PTO</div> <div><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></div> <div>(use as many sheets as necessary)</div>				<i>Complete if Known</i>	
				Application Number	
				Filing Date	
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	0801-0052.30

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	C1	YOKOYAMA, <i>et al.</i> , "Determination Of Tolperisone Enantiomers In Plasma And Their Disposition In Rats," Chemical Pharm Bull, 40(1):272-274 (1992)	
	C2	ZSILA, <i>et al.</i> , "Stereochemical Study Of Tolperisone, A Muscle Relaxant Agent, By Circular Dichroism And Ultraviolet Spectroscopy," <i>Chirality</i> , 12:720-726 (2000)	

Examiner Signature		Date Considered	
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